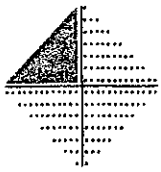

EMM
Exact Medical Manufacturing, Inc.

K101689
SEP 20 2010

Sec. 6 510(k) Summary – EMM Equipment Cover- Polyethylene

510(k) Summary for Exact Medical Manufacturing Inc., EMM Equipment Cover–Polyethylene

Date Summary was Prepared	June 10, 2010
510(k) Submitter	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Primary Contact for this 510(k) Submission	David Nowicki, President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 dnowicki@exactmm.com (p)716-681-0866, (f) 716-681-4110
Device Common Name	Equipment Cover
Trade Name	Equipment Cover- Polyethylene, ***Model # 14-001***
Device Product Codes and Classification Name	MMP, 21CFR878.4370, Surgical Drape and Drape accessories, Class II
Predicate Device	K083234 Kimberly-Clark KC100 Surgical Drapes and Equipment Covers
Device Description	Exact Medical Manufacturing Equipment Cover- Polyethylene are single use, disposable equipment cover used in the OR as a protective covering, for the operating equipment, from the transfer of microorganisms, body fluids and particulates. Exact Medical Manufacturing Equipment Covers - Polyethylene are comprised Polyethylene with absorbent polypropylene. The Exact Medical Manufacturing Equipment Covers-Polyethylene are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.
Intended Use	Exact Medical Manufacturing Equipment Cover - Polyethylene are sterile single use devices made of natural or synthetic materials intended to be used as a protective equipment covering, such as to isolate equipment from microbial and other contamination. The Exact Medical Manufacturing Equipment Covers-Polyethylene are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization
Technological Characteristics	Exact Medical Manufacturing Equipment Cover- Polyethylene has the same design, material and performance characteristics of the predicate device. ***Additional Summary and explanation of technological characteristics is included in the following Addendum A.***
Summary of Testing	Exact Medical Manufacturing Equipment Cover- Polyethylene is substantially equivalent and meets the same acceptance criteria as the predicate device/gown in K083234. Non-clinical performance testing includes: barrier properties- Level 3, tensile, tear strength, flammability, linting and sterility. All results of the testing met acceptance criteria. ***Additional Summary and explanation of non-clinical testing is included in the following Addendum B.***
Substantial Equivalence	The equipment covers described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device indentified in K083234 except for minor variations in the widths and lengths.

Addendum A.

Sec. 10: EQUIPMENT COVER Polyethylene - Predicate Device Comparison Table

Exact Medical Manufacturing - Equipment Cover - Polyethylene	Substantially Equivalent	Kimberly-Clark KC-100 Surgical Drapes & Equipment Covers - K083234 PREDICATE DEVICE
Indications for Use: Exact Medical Manufacturing Equipment Cover - Polyethylene are sterile single use devices made of natural or synthetic materials intended to be used as a protective equipment covering, such as to isolate equipment from microbial and other contamination. The Exact Medical Manufacturing Equipment Covers-Polyethylene are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.	Substantially Equivalent	**Intended Use:** Kimberly-Clark intends to market the sterile KC100 Surgical Equipment Covers which are protective barrier covers that are intended to be used to cover surgical equipment and provide a protective barrier for that equipment.
Classification and Code: Code KKX, 21CFR878.4370, Class II	Substantially Equivalent	Classification & Code, Class II, MMP
Materials & Construction: Polyethylene, absorbent polypropylene	Substantially Equivalent	Materials & Construction: Blue polyethylene, with air laid reinforcement
Sterile: ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1	Substantially Equivalent	Sterile
Sterile Packaging: Chevron peel pouch (coated paper (73gsm), PET12/PE40 film construction), individual CSR internal wrap	Substantially Equivalent	Sterile Packaging: Chevron peel pouch (coated paper, PE film construction), individual CSR internal wrap
Non-Sterile	Substantially Equivalent	Non-Sterile
Barrier properties - AATCC 42:2007, AATCC 127:2008: Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for Use in Health Care Facilities, AAMI PB70:2003 /(R)2009), Level 3 ***compliant***	Substantially Equivalent	Barrier properties: References AATCC 127:2008, INDA IST 80.6 (98), ISO 811-1981, ISO 139-1973
Tear strength - ASTM D5587-08 (no rev.) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure. ***Tear strength for Md and Cd within general industry tolerance of +/- 20%***	Substantially Equivalent	Tensile strength: NFPA 1999, 1997, ASTM D5733-99:2002, ASTM D1004-03:2003
Tensile strength - ASTM D5034-09 (no rev.) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) ***Tensile strength for Md and Cd within general industry tolerance of +/- 20%***	Substantially Equivalent	Grab Test: ASTM D 5034-95: 2001
Flammability - 16CFR1610:2010, Flammability of Clothing Textiles, Class 1 ***PASS***	Substantially Equivalent	Flammability: 16CFR1610
Lint and other particles generation in the dry state - ISO 9073-10:2003	Not Applicable	No test

Addendum B

Non-Clinical Testing Summary: EMM Equipment Cover, Model # 14-001

Test Article	Finished Good Lot Number	Reference Standard(s)	Description	Accept – Reject Criteria	Pass/ Fail	Test Lab
Model No. 14-001 Sterile	0980APA3	AATCC 42:2007 (AAMI PB70:2003 /(R)2009)	Water Resistance: Impact Penetration Test, Level 3	<1.0 gm Blotter water weight gain	Pass	Nelson Labs, Utah, USA
Model No. 14-001 Sterile	0980APA3	AATCC 127:2008 (AAMI PB70:2003 /(R)2009)	Water Resistance: Hydrostatic Pressure Test, Level 3	=/> 50 cm hydrostatic resistance	Pass	Nelson Labs, Utah, USA
Model No. 14-001 Sterile	0980APA3	16CFR1610:2010	Flammability of Clothing Textiles – Class 1	Class 1 =/> 3.5 sec. average flame spread	Pass	Nelson Labs, Utah, USA
Model No. 14-001 Sterile	0980APA3	ASTM D5587-08 (no rev.)	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	Acceptance criteria not established in recognized standard. Tear Strength for Md and Cd within general industry tolerance of +/- 20%	Pass	Nelson Labs, Utah, USA
Model No. 14-001 Sterile	0980APA3	ASTM D5034-09 (no rev.)	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Acceptance criteria not established in recognized standard. Tensile Strength for Md and Cd within general industry tolerance of +/- 20%	Pass	Nelson Labs, Utah, USA
Model No. 14-001		ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1	SAL of > 10^{-6}	Pass	SCDC, Shanghai, CN LexaMed, Ohio, USA
Model No. 14-001 Sterile	0980APA3	ISO 9073-10:2003	Lint and other particles generation in the dry state	Acceptance criteria not established in the recognized standard	Pass	Nelson Labs, Utah, USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exact Medical Manufacturing, Incorporated
C/O Mr. Robert O. Dean
Compliance Systems International, LLC
1083 Delaware Avenue
Buffalo, New York 14209

SEP 20 20

Re: K101689
Trade/Device Name: Exact Medical Manufacturing Equipment Cover-Polyethylene, Model # 14-001
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: August 20, 2010
Received: August 23, 2010

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sec. 7: Intended Use

K101689

Indications for Use Form

SEP 20 2010

Indications for Use:

510(k) Number (if known): ***K101689***

Device Name: Exact Medical Manufacturing Equipment Cover – Polyethylene, ***Model #14-001***

Indications for Use: Exact Medical Manufacturing Equipment Cover - Polyethylene are sterile single use devices made of natural or synthetic materials intended to be used as a protective equipment covering, such as to isolate **equipment** from microbial and other contamination.

The Exact Medical Manufacturing Equipment Covers-Polyethylene are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Elizabeth F. Claverie-Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101689